

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

SUB

Display Date	12-20-01
Publication Date	12-21-01
Certifier	S Reese

[Docket No. 01D-0493]

**Draft Guidance for Industry: Exemptions from the Warning Label Requirement for Juice—Recommendations for Effectively Achieving a 5-Log Reduction; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

---

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled “Exemptions from the Warning Label Requirement for Juice—Recommendations for Effectively Achieving a 5-Log Reduction.” This draft document is intended to provide guidance to fruit and vegetable juice producers about FDA’s revised recommendations for effectively achieving a 5-log pathogen reduction that is the basis for exempting juice products from the warning label requirement established by a July 8, 1998, final rule entitled “Food Labeling: Warning and Notice Statement; Labeling of Juice Products” (the juice labeling rule). A 5-log reduction is also a requirement of the January 19, 2001, final rule entitled “Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice” (the juice HACCP rule). This draft guidance describes FDA’s current recommendations for effectively achieving a 5-log pathogen reduction in juice.

**DATES:** Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance document by *[insert date 60 days after date of publication in the Federal Register]*. Comments on this guidance may be submitted at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to Jennifer A. Burnham, Center for Food Safety and Applied Nutrition (CFSAN) (address below).

Submit written comments on the document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Jennifer A. Burnham, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-260-0773, FAX: 202-205-4422.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA has revised its guidance for effectively achieving a 5-log pathogen reduction in juice. The purpose of this guidance is to encourage those juice processors not yet subject to the juice HACCP rule (e.g., small and very small processors who are not subject to the juice HACCP rule until January 21, 2003 and January 20, 2004, respectively) who are performing a 5-log reduction to attain exemption from the warning label requirement to apply effective 5-log reduction treatments based upon current science. This draft guidance also provides guidance to processors at retail who are not subject to the juice HACCP rule and who are performing a 5-log reduction to attain exemption from the warning label requirements.

In the **Federal Register** of July 8, 1998, FDA issued the juice labeling rule (63 FR 37030). That final rule requires a warning statement on fruit and vegetable juices and juice ingredients that have not been processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present. Specifically, under 21 CFR 101.17(g), juice and juice ingredients must bear a warning label if they have not been processed to achieve a 5-log pathogen reduction, or a reduction that is equal to, or greater than, the criterion established for process controls by any final regulation requiring the application of HACCP principles to the processing of juice and juice ingredients. The warning label was intended to provide a measure of public safety until final HACCP regulations could be established and implemented.

In the **Federal Register** of January 19, 2001 (66 FR 6138), FDA issued the juice HACCP rule; this rule mandates the implementation of HACCP principles and an effective 5-log pathogen reduction treatment to ensure the safe and sanitary processing of fruit and vegetable juices and ingredients. In the juice HACCP rule, FDA set forth certain criteria for achieving the 5-log pathogen reduction, which are consistent with current scientific knowledge as described in the juice HACCP rule. This draft guidance will assist juice processors in effectively achieving a 5-log pathogen reduction in a manner consistent with that knowledge.

This document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance entitled "Guidance for Industry: Exemptions from the Warning Label Requirement for Juice—Recommendations for Effectively Achieving a 5-Log Reduction" is being issued as a level 1 draft guidance consistent with GGPs. This draft guidance represents the agency's current recommendations for effectively achieving a 5-log pathogen reduction in juice. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## II. Comments

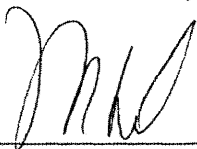
Interested persons may submit written or electronic comments to the Dockets Management Branch (address above) on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*. However, interested persons may submit written or electronic comments at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

---

### III. Electronic Access

Persons with access to the Internet may obtain the document at the CFSAN home page at <http://www.cfsan.fda.gov>.

Dated: 12/14/01  
December 14, 2001.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL

